



November 7, 2011

VIA E-MAIL (nihfoia@mail.nih.gov)

Freedom of Information Officer
National Institutes of Health
Building 31, Room 5B35
9000 Rockville Pike
Bethesda, MD 20892

Re: Freedom of Information Act Request for Records: Zhang et al. (2010),
"Occupational Exposure to Formaldehyde, Hematotoxicity, and Leukemia-Specific Chromosome Changes in Cultured Myeloid Progenitor Cells"

Dear Freedom of Information Officer:

Pursuant to the Freedom of Information Act ("FOIA"), as amended, 5 U.S.C. §§ 552 et seq., and implementing regulations promulgated by the Department of Health and Human Services ("HHS"), 45 C.F.R. Part 5, the American Chemistry Council requests copies of all Records related to the publication "*Occupational Exposure to Formaldehyde, Hematotoxicity, and Leukemia-Specific Chromosome Changes in Cultured Myeloid Progenitor Cells*" authored by Zhang et al. (2010) (the "Study") and published in the Journal of Cancer, Epidemiology, Biomarkers & Prevention. The Records requested may be a part of, or otherwise associated with, Grants R01ES01752 and P42ES004705 under the Intramural Research Program of the NIH (National Cancer Institute) and the National Institute of Environmental Health Sciences. The Records requested include the following except for the Records in Attachment A to this letter (which the National Cancer Institute already has provided in response to a previous FOIA request):

1. All Records related to the protocol and methodology for conducting the Study. These include all Records concerning:
 - a. Exclusion criteria for Study subjects.
 - b. The frequency-matching methodology that has been applied in the Study.
 - c. Statistical methods applied for evaluation of the data collected, to include assumptions related to the distribution of the aneuploid cells among individuals in the unexposed and exposed Study subjects (i.e., normal or clonal).
 - d. Methods used for conducting the Fluorescence *In situ* Hybridization (FISH) analysis, including the cutoff values for monosomy 7 and trisomy



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8, and irrespective of whether or not intact metaphases were required for analysis.

2. All Records related to the information and data obtained regarding the Study subjects. These include all Records (whether in English or Chinese) concerning:
 - a. Original questionnaires administered to Study subjects by trained interviewers requesting such information as occupational history, environmental exposures, medical history and current medications, and past and current tobacco and alcohol use.
 - b. Spreadsheets or other Records that were developed in order to summarize and/or analyze the information collected as part of the questionnaires administered to each Study subject.
 - c. Records identifying the specific factory at which each Study subject was employed.
 - d. Records identifying the specific Chinese or Western medicines used by each Study subject.
 - e. Records containing the laboratory analytical results from the exposure monitoring conducted with UME diffusion samplers worn by each Study subject.
 - f. Data and methods used for estimating 8-hr time weighted average levels for control subjects and exposed subjects.
 - g. Records that provide the Study subjects' individual clinical chemistry results, to include laboratory standardization, laboratory reference values and interlaboratory comparison statistics.
3. All Records related to any analyses, results (including but not limited to photomicrographs), findings and conclusions resulting from use of the protocol and methodology Records requested in (1) above, with respect to the information and data in the Records requested in (2) above, that have been conducted and that are not included in the published summary of the Study. These include all Records concerning:
 - a. All FISH analyses of aneuploidy measured *in vitro* in progenitor cells of exposed and non-exposed workers, to include incidence of trisomy of chromosome 7 or monosomy of chromosome 8.
 - b. All FISH analyses of aneuploidy measured by formaldehyde *in vitro* in progenitor cells.

As used in this request, the term "Records" has the meaning in 5 U.S.C. § 552(f)(2).



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I understand that pursuant to HHS's FOIA regulations, I can expect a response to this request within 10 working days of your receipt of this letter. To facilitate a timely response to this letter, please forward me interim responses as subsets of responsive records become available. Should NCI decide to withhold any responsive documents, please provide me a "Vaughn index" identifying each such document withheld and the legal basis for withholding it.

We are willing to pay reasonable fees, up to \$500, for responding to this request. If costs will exceed that amount, or if you have any questions regarding this request, please contact me at (202) 249-6139 or Laura_Brust@americanchemistry.com. Thank you for your prompt attention to this matter.

Sincerely,

A handwritten signature in black ink that reads "Laura A Brust". The signature is written in a cursive, flowing style.

Laura A. Brust
Assistant General Counsel

Attachment

